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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,050	06/29/2006	Susan Kay Hoiseth	AM100240	7930

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,050	HOISETH ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33,35 and 36* is/are rejected.

7)☒ Claim(s) *22 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Preliminary Amendment, received 29 June 2006, is acknowledged. Claim 34 is an improperly dependent claim, i.e., multiple dependent from multiple dependent claims. Therefore, claim 34 is not being considered.

2. Claims 1-33, 35, and 36 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 23, line 16, "such a" should be "such as".

Page 35, Table 1, the label (seconds) should be added, indicating what the values are in the columns, to be consistent with Tables 15-18.

Pages 38-39, Table 3, the label (seconds) should be added, indicating what the values are in the columns, to be consistent with Tables 15-18.

Page 42, Table 5, the label (seconds) should be added, indicating what the values are in the columns, to be consistent with Tables 15-18

Page 44, Table 7, the label (seconds) should be added, indicating what the values are in the columns, to be consistent with Tables 15-18

Page 47, Table 9, the label (seconds) should be added, indicating what the values are in the columns, to be consistent with Tables 15-18

Page 49, Table 11, the label (seconds) should be added, indicating what the values are in the columns, to be consistent with Tables 15-18

Page 51, Table 13, the label (seconds) should be added, indicating what the values are in the columns, to be consistent with Tables 15-18

Page 54, Table 16 is entitled as (cont.), but there is no prior Table labeled as Table 16, correction is required.

Page 55, Table 17 is entitled as (cont.), but there is no prior Table labeled as Table 17, correction is required.

Appropriate correction is required.

Claim Objections

4. Claim 22 is objected to because of the following informalities: line 2, "protein integral" should be "protein is an integral". Appropriate correction is required.

5. Claim 23 is objected to because of the following informalities: line 3, "Gonococcal" should be "gonococcal" and "Meninococcal" should be "Meningococcal". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 36 contains the trademark/trade name Triton. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a

trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a detergent, and, accordingly, the identification/description is indefinite.

8. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, because the claim recites the limitation "wherein the porin" in line 1. There is insufficient antecedent basis for this limitation in the claim because the claims from which it depends do not recite "porin".

9. Claims 9-14, 16, and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the phrase, "any of claim", but recite only one claim. It is unclear what the phrase means.

10. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, because the claim recites the limitation "wherein the integral membrane protein" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim because the claims from which it depends do not recite "integral membrane protein".

11. Claims 8-24 and 26-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 17, 26, and 29 recite in step (ii) "exchanging" the zwitterionic detergent with a nonionic detergent. However, step (iii) lists "adding" nonionic detergent, but "keeping" the zwitterionic detergent constant. It is unclear how one "exchanges", one detergent for a nonioni detergent, but then later "keeps" the zwitterionic detergent which one has removed in a

previous step. Claim 8-16, 18-24, 27, 28, and 30-33 depend from these claims, but do not clarify the issue.

12. Claims 1-33, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific agents utilized in the examples, does not reasonably provide enablement for any/all other zwitterionic agents or any/all other nonionic detergents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is drawn to compositions comprising any/all hydrophobic proteins in an amount of any/all zwitterionic detergent and in an amount of any/all nonionic detergents, methods of making said compositions less-painful for injection, and methods of reducing pain associated with administration of said compositions

The state of the prior art indicates that both zwitterionic and nonionic detergents can be utilized for solubilizing hydrophobic proteins (Matsuka et al, *J. Prot. Chem.*, 17:719-728, 1998). However, there is no data concerning utilizing any/all such detergents to reduce pain associated with injection of compositions containing said detergents.

Therefore, there is a lack of predictability in the art that any/all zwitterionic and any/all nonionic detergents are interchangeable for the purpose of reducing pain occurring during injection.

The amount of direction/guidance/working examples present in the instant application is insufficient support for the broad scope of the instant claims. The only working examples utilize Zwittergent 3-14 and Triton X-100.

Thus, because of the lack of predictability in the art and the limited species utilized in the instant specification, the quantity of experimentation necessary to expand to the entire genus of any/all zwitterionic detergents and any/all nonionic agents constitute merely an invitation to experiment without a reasonable expectation of success.

13. Claims 1-33, 35, and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific agents utilized in the examples at the specific doses recited, does not reasonably provide enablement for any/all other doses of zwitterionic agents or any/all other doses of nonionic detergents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is drawn to compositions comprising any/all hydrophobic proteins in an amount of any/all zwitterionic detergent at any/all concentrations and in an amount of any/all nonionic detergents at any/all concentrations, methods of making said compositions less-painful for injection, and methods of reducing pain associated with administration of said compositions

The state of the prior art indicates that both zwitterionic and nonionic detergents can be utilized for solubilizing hydrophobic proteins (Matsuka et al, *J. Prot. Chem.*, 17:719-728, 1998). However, there is no data concerning utilizing any/all such detergents to reduce pain associated with injection of compositions containing said detergents.

Therefore, there is a lack of predictability in the art that any/all zwitterionic and any/all nonionic detergents utilized at any/all concentrations are interchangeable for the purpose of reducing pain occurring during injection.

The amount of direction/guidance/working examples present in the instant application is insufficient support for the broad scope of the instant claims. The only working examples utilize Zwittergent 3-14 (0.05% and 0.005%) and Triton X-100 (0.06% and 0.05%).

Thus, because of the lack of predictability in the art and the limited species utilized in the instant specification, the quantity of experimentation necessary to expand to the entire genus of any/all zwitterionic detergents at any/all concentrations and any/all nonionic agents at any/all concentrations constitute merely an invitation to experiment without a reasonable expectation of success.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

June 18, 2007